

REMARKS

Status of the Claims

Claims 1-42 are pending in the present application. Claims 1, 3, 5-7, 10, 12, 18, 19, 25, 27, 30, 32, 39 and 42 are currently amended. Claim 24 is cancelled. New claims 43 and 44 have been added. In light of these amendments, and the remarks herein, reconsideration of claims 1-23 and 25-44 is respectfully requested.

Allowable Subject Matter

Applicants note with appreciation the Examiner's indication that claims 10-17 present allowable subject matter, if rewritten in independent form including all of the limitations of the base claims and any intervening claims. Applicant's have amended claim 10 in independent form including all of the limitations from claim 1 on which it previously depended, including the additional amendments made here to address the Examiner's concerns regarding 35 U.S.C. Section 112.

Amendments to the Specification

The Specification has been amended to correct several typographical errors and to substitute the number of a now-issued patent for the application serial number.

Amendments to the Claims

In light of the allowable subject matter, and to expedite prosecution of this application, Applicants present the following amendments without prejudice. Such amendments, however, provide no evidence regarding the propriety of any rejections regarding the filed claims in light of the cited art. Applicants maintain the right to pursue any of the filed claims in one or more continuing applications.

Independent claim 1 is amended to recite language that clarifies the meaning of the claim. The language is supported by the language of the original claims as well as throughout the specification.

Dependent claim 3 is amended to correct a typographical error.

Dependent claims 5 and 6 are amended to recite power density in terms of units of area, as noted in various paragraphs of the specification including paragraphs 70 and 166.

Dependent claim 7 is amended to correct a typographical error, and is consistent with the specification, including paragraph 131.

Dependent claim 10 is rewritten in independent form to include all of the limitations of independent claim 1.

Dependent claim 12 is amended to correct typographical errors.

Dependent claim 18 is amended to correct the dependency of the claim.

Independent claim 19 is amended to include the limitation of now cancelled claim 24.

Dependent claim 25 is amended to correct the dependency of the claim.

Dependent claim 27 is amended to be dependent on claim 19.

Dependent claim 30 is amended to correct a typographical error.

Independent claim 32 is amended to include the step of heating at least a portion of a tooth. Support for the amendment can be found throughout the specification, including paragraphs 74, 75, 78 and 79.

Dependent claim 39 is amended to correct a typographical error.

Independent claim 42 is amended to eliminate using a tooth stain as one of the categories of items listed to absorb optical radiation.

Since all the amendments are supported within the filed application, including the claims as originally filed, no new matter is introduced.

New Claims

New dependent claims 43 and 44 have been added. Support for the new claims can be found throughout the specification as originally filed. Specifically, support for the new

claims can be found at paragraph 120, line 7, and at paragraph 15, line 3. Accordingly, no new matter has been added by the proposed new claims.

Objections to the Specification

The Examiner objected to the specification for failing to provide the proper antecedent basis for the claimed subject matter. Specifically, the Examiner states that the specification does not mention that the chromophore may store radiation in a cumulative manner until activated, and that it is unclear how the chromophore would remain viable in the oral cavity for a 24-hour period.

The Specification does disclose and provide support for the claimed method. (See, e.g., ¶¶ 14, 15, 17 and 166.) The applicants have disclosed in detail the process of activating the chromophore over a series of sessions using power densities that are lower than those to which the chromophore is typically responsive, and, therefore, have otherwise satisfied the legal requirements to obtain a patent. For example, paragraph 17 specifically discloses that:

In another aspect, the present invention provides a method of dental treatment that includes applying non-toxic chromophores to the oral cavity and delivering a low dose of radiation to the chromophores during a session. The radiation can have a wavelength in the absorption band of the non-toxic chromophore and the dose can be lower than the power density to which the chromophore is normally responsive. In subsequent sessions, the step of applying radiation is repeated until the chromophore is activated. The chromophore is preferably a tooth whitening and brightening agent and/or an antimicrobial agent, which in one embodiment, is applied as a film having chromophores positioned therein. As an additional step, heat and/or an additional chromophore can be applied to the oral cavity.

Similarly, as another example, paragraph 166 provides specific parameters for certain embodiments of the claimed method:

In another aspect of the invention, biostimulating and/or dental phototherapies are disclosed for conditions that are normally responsive to a known power density of phototherapeutic radiation (1-10 treatments spaced 1-30 days). However, in the present invention a series of temporally spaced treatment sessions are delivered to a patient, where each session provides a power density of therapeutic radiation lower than typical power density needed to treat the condition according to the conventional protocols. The method can comprise the steps of selecting a condition normally responsive to oral

application of a known power density of phototherapeutic radiation, and delivering a series of temporally spaced treatment sessions to a patient. Each session provides a power density of therapeutic radiation lower than the typical power density needed to treat the patient condition. The series of temporally spaced treatment sessions can be continued until the patient's condition is ameliorated by a cumulative effect of the series of treatment sessions. The power density applied to the patient's skin surface is between approximately 1 mW/cm² and approximately 100 W/cm², and depends at least on the condition being treated and the wavelength of the radiation. Preferably, the energy at the tooth or mucosal surface is between 10 mW/cm² and 10 W/cm². The radiation can be applied for a duration of one second to one hour. Energy flux can be in the range of about 1 J/cm² to 1000 J/cm², and preferably in the range of about 10 J/cm² to 100 J/cm². In many embodiments, an emitting area of an LETM or LEMP can be in a range of about 0.1 to about 100 cm² and the power delivered is in a range of about 1mW to about 10 W, and preferably in a range of about 10 mW to about 1 W.

Therefore, the specification contains sufficient disclosure to provide antecedent basis for the claimed subject matter.

Objections to the Claims

The Examiner objected to claim 7 due to the reference to "1400000 nanometers." Accordingly, the Applicants have amended the claim to refer to "1,400 nanometers," as referred to in the specification at paragraph 131.

Claim Rejections - 35 U.S.C. § 112

Claims 1-18, 24-25 and 30-31 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention.

The Examiner rejected claim 1, because "the radiation step dosage being lower than that required to activate the chromophore" also will not activate the chromophore when the step is repeated. The Applicant has amended the claim to clarify that the single dosage applied in a given step of the method has a dose that is lower than the dose to which the chromophore is normally responsive when a single dose of radiation is applied. Thus, the language of the claim is now clear that a dose of radiation can activate the chromophore when applied in combination with additional doses applied in the course of multiple steps.

The Examiner rejected claims 5 and 6 because they recite a power density in units of watts without relation to a unit of area. Accordingly, Applicants have amended claims 5 and 6 to recite a power density in units of watts per square centimeter, as disclosed in the specification at, *e.g.*, paragraphs 70 and 166.

The Examiner rejected claim 25, because the phrase “the target region” did not have sufficient antecedent basis. Accordingly, Applicants have amended claim 25 to be dependent on claim 19, which provides the proper antecedent basis for the phrase “the target region” in claim 25.

The Examiner rejected claim 30, because it was unclear. Accordingly, Applicants have amended the claim to correct a typographical error, which Applicants believe alleviates the Examiner’s concern.

In light of the statements above and the amendments to claims 1, 5, 6, 25 and 30, the rejected claims particularly point out and distinctly claim the subject matter of the invention. Accordingly, the pending claims meet the requirements of 35 U.S.C. §112, second paragraph.

Claim Rejections - 35 U.S.C. § 102

Claims 1-3 and 5-9 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,942,658 to Rizioiu et al. (herein “Rizioiu”). These claims are novel, however, because Rizioiu fails to disclose all of the elements recited in the claims. For example, Claim 1 recites “delivering a dose of radiation to the chromophore during a session, ... the dose being lower than the power density to which the chromophore is normally responsive when a single dose is applied.” Claim 1 further recites “delivering additional doses of radiation in subsequent sessions until the chromophore is activated.”

Rizioiu does not disclose these elements of the claimed invention. Rizioiu refers to a chromophore in only two locations in the patent, and does not provide details for how to employ a chromophore. (Rizioiu Col. 7:19 and 7:44.) More specifically, Rizioiu does not address the activation of the chromophore anywhere in the specification, and, thus, cannot teach or suggest the present invention. Rizioiu only states that a chromophore may activate the whitening agent, and does not address radiating a chromophore over a series of sessions

using dosages to which the chromophore is normally not responsive during any one session. (Rizoiu Col. 7:44.) Rizoiu actually teaches the opposite, because it discloses the use of “a target chromophore...strongly absorbed by laser wavelengths in the infrared from 700 nm to 3 microns.” This disclosure implies that the chromophore is to absorb as much energy as possible and, thus, teaches away from applying radiation at doses that are below energy required to activate the chromophore. (Rizoiu Col. 7:19.)

In comparison, Applicants teach “a series of temporally spaced treatment sessions are delivered to a patient, where each session provides a power density of therapeutic radiation lower than typical power density needed to treat the condition according to the conventional protocols.” (Application ¶ 166.) Although, Rizoiu may teach a series of treatments, it does not teach or suggest using a dose below that required to activate the chromophores in any given session.

Claims 2-3 and 5-9 are novel for at least the same reasons that Claim 1 is novel. Accordingly Claims 1-3 and 5-9 are novel and patentable over Rizoiu.

Claims 19-23 and 26-34 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,879,159 to Cipolla (herein “Cipolla”). These claims are novel, however, because Cipolla fails to disclose all of the elements recited in the claims. Specifically, Cipolla does not disclose heating a target region of a tooth to achieve the desired result. On the other hand, Claim 19 as amended recites “heating the target region.” Similarly, Claim 26 recites “thermobleaching a target region of the tooth with optical radiation,” and claim 32 recites “heating said portion of said tooth.”

Claims 20-23, 27-31 and 33-34 are patentable for at least the same reasons that claims 19, 26 and 32 from which they depend are patentable. Accordingly Claims 19-23 and 26-34 are novel and patentable over Cipolla.

Claims 35 and 37-41 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Publication No. 2003/0152528 to Singh et al. (herein “Singh”). These claims are novel, however, because Singh fails to disclose all of the elements recited in the claims. Claim 35 recites a “chromophore being activated in response to radiation in a selected bandwidth to cause whitening of the teeth.”

Singh does not disclose that element of the claimed invention. Instead, Singh discloses a whitening composition that does not include a light-activated or radiation activated process or element. As noted in the abstract, Singh discloses that:

A composition is provided, wherein the composition comprises a water-swellaable, water-insoluble polymer, a blend of a hydrophilic polymer and a complementary oligomer capable of hydrogen bonding to the hydrophilic polymer, and a whitening agent, preferably a peroxide. The composition finds utility as a tooth whitening composition and is applied to the teeth in need of whitening, and then removed when the degree of whitening has been achieved.

Though the present office action states that the process in Singh “may be light activated,” the disclosure from Singh that the office action refers to actually is a discussion of prior art and is not part of the invention disclosed by Singh. Furthermore, the cited passage refers to using light to cure a protective coating used in “in-office” whitening compositions that employ hazardous oxidizing agents. The cited passage states: “the soft tissue may be isolated from the oxidizers to be used in the whitening process by covering the soft tissue with a polymerizable composition that is shaped to conform to the gingival contours and subsequently cured by exposure to a high intensity light source.” (Singh ¶ 20.) The reference to high intensity light is not to whiten the teeth; it is only to cure the protective coating used in the process. With the exception of using light to cure a dental composition, Singh does not disclose the use of optical radiation to achieve tooth whitening or other results.

Claims 37-41 are patentable for at least the same reasons that claim 35 is patentable. Accordingly Claims 35 and 37-41 are novel and patentable over Singh.

Claim Rejections - 35 U.S.C. § 103

Claims 4, 17, 18 and, 25

Claims 4, 17, 18 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,942,658 to Rizoiu in view of U.S. Patent 6,106,293 to Wiesel (herein “Wiesel”).

Claims 4, 17 and 18 are not obvious, because Rizoiu teaches a procedure that is contrary to that of the claimed invention. Initially, there is no stated motivation to combine the cited references. Further, the combination would not yield the claimed invention. Specifically, as stated above, Rizoiu actually has teachings that are inconsistent with the claimed invention. Rizoiu discloses the use of “a target chromophore...strongly absorbed by laser wavelengths in the infrared from 700 nm to 3 microns.” This disclosure implies that the chromophore is to absorb as much energy as possible and, thus, teaches away from applying radiation at doses below that required to activate the chromophore. Thus, even if there were a motivation to combine the references, the combined references would result in applying large doses of energy to activate the chromophore, whether using a film as in claim 4, or by also applying heat at in claims 17 and 18.

Claims 25 is not obvious in view of Rizoiu as applied to claim 1, because, as amended, claim 25 is dependent on independent claim 19, whereas Rizoiu was applied to claim 1. As discussed above, Applicants amended the dependency of claim 25 from claim 1 to claim 19 to correct a problem with the antecedent basis in the claim and overcome an objection to the claim.

Claim 36

Claim 36 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0152528 to Singh in view of the art. Because Singh does not disclose a process that is similar to the claimed invention or that is light activated, it would not be obvious to employ ethylene oxide in Singh’s processes to achieve the claimed invention.

Claim 42

Claim 42 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 65,879,159 to Cipolla in view of U.S. Patent 6,525,819 to Delawter et al. (herein “Wiesel”).

Claim 42 is not obvious, however, because, as noted by the Examiner, Cipolla teaches only that the stain in the tooth may absorb light to facilitate whitening. Although Applicants

dispute that this is the use of the stain as disclosed in the present application, they have amended the claim to delete reference to use of the stain itself as a chromophore.

Furthermore, Claims 4, 17, 18, 25, 36 and 42 are each patentable for at least the same reasons that Claim 1 is patentable.


CONCLUSION

In view of the amendments and remarks above, Applicants submit that claims 1-23 and 25-44 are in condition for allowance, and allowance thereof is respectfully requested. Applicants encourage the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

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Respectfully submitted,

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